

REMARKS

Status of the Claims

Claims 1-20 are pending as shown above. Claims 10-20 have been canceled, without prejudice or disclaimer. Applicants reserve the right to file one or more continuation or divisional applications directed to the subject matter of the canceled claims.

Claim 1 has been amended as shown above to clarify that the methods select any dimerizing polypeptide and, in addition, to specify that the dimerization occurs between two identical fusion proteins. Claims 3 and 4 have also been amended to conform to the language of amended claim 1. Support of these amendments can be found throughout the specification as filed, for example on page 73, line 30 to page 74, line 15 and Figure 11.

Dimerization

The Advisory Action mailed on September 13, 2004 indicating that Applicants had not pointed, with particularity, as to wherein the specification support may be found for dimerization of the entire fusion protein, or some portion of the fusion protein other than the test polypeptide.

Applicants direct the Examiner's attention to page 73, line 30 to page 74, line 15 where it is noted that:

In another aspect, the interaction trap system of the present invention can be used to identify polypeptides capable of dimerizing (Figure 11). A chimeric transcription factor [fusion polypeptide] containing one or more DNA binding domains is fused to a library of random test peptides. The reporter gene is fused to a promoter.... Binding of a single copy of the transcription factor to the promoter is unable to induce a significant amount of transcription of the reporter gene. However, upon dimerization of the transcription factor leading to two copies being bound to the promoter region, transcription of the reporter gene is significantly increased.

In various embodiments, the dimerization might occur due to an interaction between the random test polypeptide portions of the transcription factor molecules. Alternatively, the dimerization could be driven by an interaction between the random test polypeptide and one copy of the transcription factor and the DNA binding domain of the other copy of the transcription factor.

Thus, the specification clearly describes how dimerization occurs between two copies of the same fusion protein and, moreover, how dimerization may be via interactions between any of the components of the fusion protein.

35 U.S.C. § 112, First Paragraph, Enablement and Written Description

The enablement and written description rejections set forth in the Final Office related to the now-canceled recitation "introducing a DNA library ..." (Final Office Action, paragraphs 9 and 19, where it was noted that the rejection was necessitated by applicant's previous amendment to the claim 1). Nonetheless, the Advisory Action subsequently indicated that there are now enablement and description rejections regarding the scope of the term "reporter gene." (Advisory Action, page 2).

Applicants note that it is improper to introduce new grounds of rejection in an Advisory Action. Nonetheless, Applicants address the improperly raised rejections below.

Written Description

Because the genus of reporter genes is adequately described in the specification as filed, Applicants traverse the rejection and supporting remarks.

The fundamental factual inquiry in written description is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. Determining whether the written description requirement is satisfied is a question of fact and the burden is on the Examiner to provide evidence as to why a skilled artisan would not have recognized that the applicant was in possession of claimed invention at the time of filing. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Wertheim*, 191 USPQ 90 (CCPA 1976). Finally, determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by the skilled artisan at the time of filing, for example as established by reference to patents and publications available to the public prior to the filing date of the application. *See, e.g., In re Lange*, 209 USPQ 288 (CCPA 1981).

The Patent Office's own guidelines on written description are clear -- the written description requirement is highly fact-dependent and there is a strong presumption that an adequate written description of the claimed invention is present at the time of filing:

[t]he description need only describe in detail that which is new or not conventional. This is equally true whether the claimed invention is a product or a process. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that the applicant was in possession of the claimed invention, i.e. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with known or disclosed correlation between function and structure, or some combination of such characteristics. ... (Final

Examiner Guidelines on Written Description, 66 Fed. Reg. 1099, emphasis added).

Simply put, satisfaction of the written description requirement is not dependent on providing working examples regarding each and every possible reporter gene. The allegedly broad genus of reporter genes is described throughout the specification, for example, pages 38-42, describing exemplary reporter genes including HIS3, 3-AT, β -lactamase enzymes (page 41, lines 3-11), and/or one or more fluorescently active polypeptides (page 42, lines 9-17). Moreover, the structures and functions of these reporter genes were entirely conventional and known at the time of filing.

In view of these facts and the failure of the Office to provide evidence as to why the skilled artisan would not have understood that Applicant was in possession of the subject matter of the claims as previously presented, withdrawal of this rejection is in order.

Enablement

Similarly, the specification as filed fully enables one of skill in the art to practice the claimed methods using any suitable reporter gene.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). Accordingly, in the pending case, Applicant is in no way required to show each and every reporter gene that may be used. All that is required is that the specification teaches a skilled practitioner how to practice methods as claimed in which a reporter gene is used to detect dimerization. As set forth throughout the specification as filed, a wide variety of reporter genes may be used in these methods. *See, e.g.*, pages 38-42, describing exemplary reporter genes including HIS3, 3-AT, β -lactamase enzymes (page 41, lines 3-11), and/or one or more fluorescently active polypeptides (page 42, lines 9-17).

Thus, the specification as filed more than satisfies the enablement requirement, as it clearly sets forth how to practice the claimed methods using any reporter gene. The skilled artisan could readily select any reporter gene from the recited lists or known in the art in which the practitioner is presumably already interested, according to the disclosure, and test whether or not dimerization can be evaluated, again according to the disclosure.

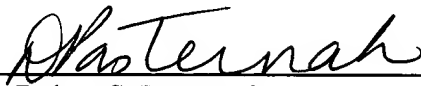
Thus, Applicants submit that the specification fully enables methods as claimed, regardless of the reporter gene. Because the claims as presently presented are of reasonable scope and are fully enabled by the specification as filed, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing remarks, Applicants submit that all pending claims are in condition for allowance and request early notification to that effect. Should the Examiner have any further questions, he is invited to contact the undersigned.

Respectfully submitted,

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